K040354

NOV - 4 2004

EXHIBIT Ib

Summary of Safety and Effectiveness

Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name: Metal/Metal Hip System

Common Name: Total Hip Prosthesis, Semi-constrained

Classification Name: Hip joint metal/metal semi-constrained with an uncemented acetabular component prosthesis, 21CFR 888.3330

Description: The metal/metal hip system consists of metal femoral heads and an acetabular cup. The acetabular cup is a metal shell with a polyethylene liner that has a machined feature to accept a metal articulating inlay. The polyethylene components are manufactured from materials conforming to ISO 5834-2 and the metal components are manufactured from materials conforming to ASTM F799. The design features of these parts are identical to those previously cleared under K003250.The metal shells are available with outside diameters of 48mm to 66mm (in 2mm increments). The shells accept a polyethylene liner with a metal articulating inlay with inner diameters of 28mm, 32mm, 34mm, and 38mm. The femoral heads are available in diameters of 28mm, 32mm, 34mm, and 38mm. The size changes referenced in this 510(k) are the additional 32mm, 34mm, and 38mm components.

Intended Use: The Metal/Metal Hip System used in total hip replacement is intended for conditions of degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same materials, design, and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2004

Ms. Debbie De Los Santos
Supervisor, Regulatory/Clinical Affairs
Encore Medical L.P.
9800 Metric Boulevard
Austin, Texas 78758

Re: K040354
Trade/Device Name: Metal/Metal Hip System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: October 5, 2004
Received: October 6, 2004

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): K040354

Device Name: Metal/Metal Hip System

Indications for Use:

Indications for use in total hip replacement include: degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040354